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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,056	SORNDAL, GOSTA	
	Examiner	Art Unit	
	Michael Wieczorek	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17* is/are rejected.

7)☐ Claim(s) *16 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/30/2006, 11/24/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 3 is objected to because of the following informalities: the preamble of the claim recites "microchannel microchannel structures". Appropriate correction is required.

2. Claims 16 and 18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 16 and 18 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim discloses that the steps of reducing the gas pressure in the vessel (step (i)), bringing into contact the liquid phase with at least one port if this was already done so in step (i), and increasing the gas pressure in the vessel while a major portion of the microchannel structure is placed outside the vessel and at least one inlet port is communicating with the interior of said vessel. While this limitation is disclosed within the specification there is nothing in the claims detailing how this particular application is

conducted or possible within the confines of the disclosed claims. Claim 4 from which claim 6 depends on discloses that the vessel is closed but nothing in the claims discloses how a major portion of each microchannel structure can be outside the vessel and at least one inlet port is inside the vessel while it is closed.

Attention is directed to *In re Wands*, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. The factors include:

1) *The nature of the invention:*

The instant invention is drawn to an invention of surface modifying microchannels of a microfluidic device utilizing reduced pressure to fill the microchannels with a surface modifying liquid.

2) *The state of the prior art:*

The art does teach surface modifying the microchannels and using reduced pressure to fill the microchannels of microfluidic devices but it does not recognize that using reduced pressure to fill in the microchannels is possible while a major portion of the microchannel structure is outside a vessel capable of pressure reduction while an inlet port is also communication with the interior of the vessel.

For example, Monahan et al (NPL Document, *A Method for Filling Complex Polymeric Microfluidic Devices and Arrays*) teaches method of filling the microchannels of a microfluidic device using reduced pressure. Monahan et al teaches reducing the gas pressure in a vacuum chamber while the inlet ports of the microfluidic device are in contact with a liquid phase contained in the chamber

and then increasing the gas pressure in the vessel after a suitable incubation period but all of this occurs while a major portion of the microchannel structures of the device are inside the vessel.

Thus the art in itself does not recognize, teach or suggest carrying out steps (ii)-(iv) while a major portion of the microchannel structure is placed outside the closed vessel and while at least one inlet port is communicating with the interior of the closed vessel.

3) *The predictability of the art:*

There is a high degree of predictability in utilizing reduced pressure to fill the microchannels of a microfluidic device. As disclosed in the reference Monahan there are several known method for utilizing reduced pressure to fill the microchannels with a liquid including utilizing a reduced pressure. The reference of Monahan discloses that bubble-free filling is possible by placing the microfluidic device, thus a major portion of the microchannel structure, in a closed vacuum chamber during filling.

4) *The amount of guidance/working examples:*

As discussed, the specification discloses this limitation as a possible variation of the claimed method but provides no guidance or working examples on how to carry out steps (ii)-(iv) while a major portion of the microchannel structure is placed outside the closed vessel.

5) *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art would not be able to carry out steps (ii)-(iv) while a major portion of the microconduit was placed outside the closed vessel and at least one pot is communication with the interior of said closed vessel.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. As for claim 4, it is not immediately clear if the disclosed steps are in addition to those disclosed in claim 1 or if the disclosed steps are a further description of the filling step (I) which utilizes reduced pressure. The specification of the present case discloses that claim 4 is directed to the filling step (I) (Page 6 Line 30 through Page 7 Line 13), but this information is not conveyed in any of the claims. Clarification on this issue is requested.

8. Claims 14 and 15 recites the limitation "the first round or in a repetitive round". There is insufficient antecedent basis for this limitation in the claim. Claims 1 from which these claims depend on does not recite the limitation of "the first round" nor does claim 1 establish that disclosed method can be repeated so that there is a first round.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-7, 10, 12-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (U.S. Patent # 6,326,083) in view of Monahan et al (NPL Document, *A Method for Filling Complex Polymeric Microfluidic Devices and Arrays).*

Yang teaches a method of surface modifying a microfluidic device by coating the microchannel of the device with a hydrophilic protein adsorption resistant coating (Abstract and Column 2 Lines 11-25). Specifically, the method of Yang is for treating devices comprising at least one microchannel (Column 21 Lines 47-57).

The microfluidic device of Yang comprises a plurality, thus two or more, microchannel structures comprising a microconduit or microscale groove 16 which are communication with a plurality of ports 24 (Column 15 Line 59 through Column 16 Line 2 and Figure 1) and each port 24 is in communication with at least one microconduit 16 and these ports allow for introduction

of fluids into the microchannels (Column 16 lines 3-20 and Figure 1). Furthermore, Yang teaches that the devices are comprised of polymeric materials such as polydimethylsiloxane (PDMS) (Column 15 Lines 35-52).

The method of surface modification taught by Yang comprises filling the microchannels of a microfluidic device, and thus the microconduits, with a coating solution/surface modification liquid, incubating the solution in the microchannel and then removing the liquid from the microchannel (Column 24 Lines 5-15).

Yang does not however specifically teach that the microconduit is filled through at least one of the ports nor that reduced pressure is utilized in the filling step.

Monahan teaches a method of filling microfluidic structures with aqueous solution using a channel outgas technique (COT) based on a filling procedure carried out at reduced pressure (Column 1 Paragraph 1, Page 3193). Monahan further teaches that the taught method is suitable for filling PDMS-based microfluidic devices having complex channel structures (Column 1 Paragraph 2, Page 3194). The method of Monahan utilizes microfluidic devices similar to that taught by Yang in that the device comprises a molded polymer pattern sealed with a second polymer flat to generate channel networks in the interior of the device and reservoir or ports where punched in the surface of the device to provide access to the interior channels (Column 1 Paragraph 4, Page 3194). Thus the microfluidic devices of Yang and Monahan comprise ports (PT) communication with ambient atmosphere and are also in communication with the interior microconduits of the device.

The method of Monahan further comprises taking the above described device and submerging it in a solution contained in a vacuum chamber vessel. Then pressure in the vessel

was decreased so as to cause the solution to fill the interior microconduits of the device through the open ports/reservoirs. After a period of incubation the pressure in the vessel is returned to atmospheric pressure and the liquid is removed from the device. Furthermore, the method taught by Monahan can be used to perform multiple treatments on the same device. (Column 1 Paragraph 7 through Column 2 Paragraph 2, Page 3194 and Figure 1(c)).

Furthermore, Monahan teaches that the taught invention allows for bubble-free filling of microfluidic devices comprising complex patterns (Page 3197, Conclusion Section).

At the time the present invention was made it would have been obvious to fill the microconduit through one of the at least one ports of the microfluidic device by utilizing reduced pressure. It would have been obvious to perform the surface modification method of Yang by using the filling method of Monahan since the method of Monahan allow for bubble-fee filling of microchannels of microfluidic devices.

As for claim 2, as was discussed above, the microfluidic devices taught by Yang comprises two or more microchannel structures. Furthermore, the method of Monahan has the filling and incubation steps (I) and (II) being carried out in parallel for the two or more microchannel structures since the entire device is submerged in the solution during the filling and incubation steps.

As for claim 3, as is shown in Figure 1 of Yang the microconduit parts 16 are communicating with a port 24 at one end of the device and another port 24 at the other end of the device. Furthermore, a similar configured microfluidic device is shown in Figure 1(c) of Monahan. As for the limitation that the liquid is sucked through one or more ports by applying reduced pressure at another port, the COT method described above and taught by Yang

comprises using reduced pressure to suck gas on of the channels through the reservoirs/ports which allows for fluid to fill in or be sucked into the channels through the reservoirs/ports (Column 2 Paragraph 3, Page 3195 through Column 1 Paragraph 1, Page 3196).

Monahan further teaches a second known filling method wherein a vacuum is applied to one port at one end of a microconduit while liquid is sucked into the port at the other end of the microconduit (Column 1 Paragraph 6, Page 3194 and Figure 1(b)).

As for the limitation that the remaining ports are closed, since all the ports in the methods taught by Monahan are being utilized for filling or applying reduced pressure, the remaining ports would inherently be closed/non-existent. Furthermore, Monahan teaches that the primary COT method can be used to fill channels utilizing only one reservoir/port for filling (Column 2 Paragraph 2, Pages 3196), thus the remaining ports would be closed/non-existent.

As for claim 4, as was discussed above, the method of Monahan teaches step i) in that the taught method utilizes a closed vacuum vessel comprising a liquid phase/surface modification agent and a gas phase (Figure 1(c)) and that before filling the microchannels are empty and filled by submerging/contacting the ports/reservoirs with the liquid phase. Furthermore, as was discussed above pressure is reduced while the device is submerged in the gas phase causing the channels to fill and after a period of incubation pressure is increased back to atmospheric pressure.

As for claim 5, as was discussed above, the method of Monahan comprises reducing the pressure (step (ii)) and increasing the pressure (step (iv)) while the device is in the vacuum vessel.

As for claim 6, Monahan teaches an alternative embodiment to the above discussed immersion/vacuum filling method. Monahan teaches that it may not be desirable to submerge and entire device in a solution, so a vessel or extension reservoir which contains the fill liquid and a gas phase. The extension reservoir is in communication with at least one port/reservoir of the device and since the extension reservoir does not encompass the device as show in Figure 5(a), it can be considered that Monahan teaches a method wherein the device, and thus at least a major portion of each of the microchannel structures, is placed outside of a vessel/extension reservoir and Monahan further teaches that reducing and increasing of pressure is still utilized to fill the microchannels. (Column 2 Paragraph 2, Page 3196 through Column 1 Paragraph 1, Page 3197 and Figure 5(a))

As for claim 7, as was discussed above in the claim 6 rejection, Monahan teaches an embodiment wherein a capillary tube or extension reservoir is attached to a port of the microfluidic device during the taught method.

As for claim 10, as was discussed above, both Yang and Monahan teach rinsing the device after filling the microchannels, thus the fill liquid is at least partial removed by replacing the fill liquid with another fluid.

As for claim 12, the surface modification method of Yang allows for multiple coating steps (Column 22 Lines 9-14) and as was discussed above in the claim 1 rejection, the method of Monahan allows for multiple filling treatments of the device. Furthermore, as for the liquid used in step (I) is would have to be either the same or of a different composition as the liquid used in a previous round.

As for claim 13, as was discussed above in the claim 11 rejection, the method of Yang allows for multiple coating steps of applying multiple surface modification liquids which would have to be either the same kind or of a different kind of coating liquid as used in the first round.

As for claim 14, Yang teaches a surface modification method where hydroxyethylated poly(ethyleneimine) (PEI) is adhered to or captured by the inner surface of the microchannel (Column 23 Line 59 through Column 24 Line 18). The PEI can be considered an analyte because it is determined or analyzed in a subsequent process to determine the effective of surface modified channels against adsorbing proteins (Column 23 Lines 25-29).

As for claim 15, Yang teaches a surface modification method where the filling solution comprises 3-glycidoxypropyl trimethoxysilane which is adhered to or captured by the surface of the microchannel (Column 31 Lines 39-67). This component can be considered a reagent or reactant because is it used in a subsequent process to form a positive or negatively charged poly(ethyleneglycol) coating on the surface of the device (Column 32 Lines 1-8).

As for claim 17, in the surface modification method of Yang the coating solution comprises the surface modifying agent (the polymeric component 8% PEI-1 in the reference) and liquids in the form of ethanol and water (Column 24 Liens 9-16). Both ethanol and water are used as the liquid component in the coating solution of the examples taught in Yang and both water and ethanol have boiling points greater than 70 °C.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al in view of Monahan et al as applied to claim 4 above, and further in view of Kinoshita et al (U.S. Patent Publication No. 2002/0150832).

The teachings of Yang in view of Monahan as they apply to claim 4 have been discussed previously. Furthermore, as was discussed above in the claim 18 rejections, Yang teaches a desire to produce multiple microfluidic devices having the same surface modification so as they can be used for the same purpose. Furthermore, Monahan teaches using a holder for the device in the form of a glass slide which allow for the device to be submerged in the liquid (Column 1 Last Paragraph, Page 3194). But neither reference teaches that a holder capable of holding a plurality microfluidic devices.

Kinoshita teaches a method of coating a plurality of substrates by immersing the substrates in a bath containing the coating liquid (Abstract). The method of Kinoshita comprises utilizing a holder capable of holding a plurality of substrates to be immersed in the coating material (Pages 1-2 Paragraph 0012), thus Kinoshita teaches that is it possible to immerse and coat a plurality of substrates by utilizing a single holder adapted to hold the plurality of substrates.

At the time the present invention was made it would have been obvious to use a holder capable of holding a plurality of microfluidic devices. Based on the teachings of Kinoshita, it would have been obvious to one of ordinary skill that multiple microfluidic devices can be filed at once using the method of Yang in view of Monahan by modifying the glass slide holder of Monahan to be able to hold multiple microfluidic devices.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al in view of Monahan et al as applied to claim 1 above, and further in view of Rosynsky et al (U.S. Patent # 5,866,210).

The teachings of Yang in view of Monahan as they apply to claim 1 have been discussed previously. Neither Yang nor Monahan teach removing the liquid introduced into the microconduit by evaporating the liquid out of one the ports.

Rosynsky teaches an invention related to coating a substrate comprising a plurality of channels by using reduced pressure (Abstract and Column 1 Lines 7-10). The coating material of Rosynsky is a slurry, thus a liquid-based coating material (Column 3 Lines 40-45). The method of Rosynsky comprises that after the coating is applied to the channels the coating material is dried, thus the liquid phase of the coating is removed, by applying a vacuum/reduced pressure to withdraw vapors from the evaporated liquid phase out of the channels, thus evaporating the liquid out of the channels by way of the channel openings of ports (Column 5 Lines 51-57).

At the time the present invention was made it would have been obvious to remove the liquid from the microconduits by evaporation the liquid out of at least one port. Based on the teachings of Rosynsky, one of ordinary skill in the art would have a reasonable expectation of success in removing the filled in liquid of the method of Yang in view of Monahan by evaporating the liquid by applying reduced pressure to draw out the vapors of the evaporated liquid because this is a known method for drying liquid-based coating material in the art.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al in view of Monahan et al as applied to claim 1 above, and further in view of Tooke et al (International Patent Publication No. WO 01/47638).

The teachings of Yang in view of Monahan as they apply to claim 1 have been discussed previously. Neither Yang nor Monahan teach utilizing a microfluidic device that permits the use of centrifugal force for removing the liquid. Yang does teach that the taught microfluidic devices are those used as assays and as devices for genetic analysis (Column 16 Lines 34-47).

Tooke teaches a microfluidic device that is disc shaped and is used for nucleic acid sequencing (Page 1 Lines 3-6). Tooke further teaches that the taught disc microfluidic device can be comprises of plastics or polymers and can be surface modified to provide the requisite hydrophilicity to the surfaces of the device (Page 12 Line 25 through Page 13 Line 3). Furthermore, Tooke teaches a method of preparatory surface modification of the device utilizing liquid suspension wherein the liquid is removed form the channels of the device utilizing centrifugal force cause by spinning the device (Page 14 Line 14 through Page 15 Line 6). Thus the microfluidic device of Tooke permits the use of centrifugal force for removal of liquid from the microchannels of the device and teaches that a known removal process of liquid from the microchannels of the device is to use centrifugal force.

At the time the present invention was made it would have been obvious to use a microfluidic device that permits the use of centrifugal force for removing a liquid from the microchannels. It would have been obvious to use the microfluidic disc of Tooke in the surface modification step of method of Yang in view of Monahan because the device of Tooke is used in genetic analysis and requires hydrophilic surface modification as taught by Yang.

Furthermore, it would have been obvious to utilize the centrifugal removal process of Tooke on the device since this is a known and taught process for liquid removal from the microchannels of the device.

As for the transferring of the device to a centrifugal device adapted to create the centrifugal force, this would be apparent to one of ordinary skill because the filling apparatus of Yang in view of Monahan is not capable of creating centrifugal force thus the filled device would have to be transferred to a device capable of creating the required force.

Conclusion

Claims 1 through 15 and 17 have been rejected. Claims 16 and 18 have been withdrawn from consideration as being improper multiple dependency claims. No claims were allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Wieczorek whose telephone number is (571)270-5341. The examiner can normally be reached on Monday through Friday; 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Cleveland can be reached on (571)272-1418. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Wieczorek/
Examiner, Art Unit 1792

/Michael Cleveland/

Supervisory Patent Examiner, Art Unit 1792